Privacy & Security Policy Workgroup
Draft Transcript
April 8, 2010

Presentation

Judy Sparrow – Office of the National Coordinator – Executive Director
Thank you. Good afternoon and welcome everybody to the Privacy & Security Policy Workgroup. This is a federal advisory committee, and there will be opportunity at the end of the meeting for the public to make comment. Let me just do a quick roll call. Deven McGraw?

Deven McGraw - Center for Democracy & Technology – Director
Here.

Judy Sparrow – Office of the National Coordinator – Executive Director
Rachel Block? Latanya Sweeny? Gayle Harrell?

Gayle Harrell – Florida – Former State Legislator
Here.

Judy Sparrow – Office of the National Coordinator – Executive Director
Paul Tang? Mike Klag?

Mike Klag – Johns Hopkins Bloomberg School of Public Health – Dean
Here.

Judy Sparrow – Office of the National Coordinator – Executive Director
Judy Faulkner? John Blair?

John Blair – Tacanic IPA – President & CEO
Here.

Judy Sparrow – Office of the National Coordinator – Executive Director
Paul Egerman?

Paul Egerman – eScription – CEO
Here.

Judy Sparrow – Office of the National Coordinator – Executive Director
Dixie Baker?

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
Here.

Judy Sparrow – Office of the National Coordinator – Executive Director
Paul Uhrig? Dave Wanser?

Dave Wanser – NDIIC – Executive Director
Here.

Judy Sparrow – Office of the National Coordinator – Executive Director
Kathleen Connor?

Kathleen Connor – Microsoft Health Solutions – Principal Program Manager
Here.

Judy Sparrow – Office of the National Coordinator – Executive Director
Laurel Stein? Terri Shaw? John Houston?

John Houston – Univ. Pittsburgh Medical Center – VP, Privacy & Info Security
Here.

Judy Sparrow – Office of the National Coordinator – Executive Director
Joyce DuBow?

Joyce DuBow – AARP Public Policy Institute – Associate Director
Here.

Judy Sparrow – Office of the National Coordinator – Executive Director
Mike DeCarlo is on for Justine Handelman. Mike? Connie Delaney?

Mike DeCarlo – BlueCross BlueShield
I'm here. I'm sorry. I was on mute.

Judy Sparrow – Office of the National Coordinator – Executive Director
Okay. Connie Delaney? Marianna Bledsoe?

Marianna Bledsoe – NIH – Deputy Associate Director
Here.

Judy Sparrow – Office of the National Coordinator – Executive Director
Peter Basch?

Peter Basch – MedStar Health – Medical Director
Here.

Judy Sparrow – Office of the National Coordinator – Executive Director
Sue Mc Andrew?

Adam Green – OCR
Adam Green is here.

Judy Sparrow – Office of the National Coordinator – Executive Director
Okay, Adam. I believe, on the phone, we have from ONC, Suniti is in the room here with me, and Joy Pritts, are you on?

Joy Pritts – ONC – Chief Privacy Officer
Yes, I am.

Judy Sparrow – Office of the National Coordinator – Executive Director
Anybody else on from HHS? Okay, Deven, back to you.

Deven McGraw - Center for Democracy & Technology – Director
Terrific. Thank you, all. We have a good compliment of workgroup folks on the phone, at least for the first hour, which is terrific. Thanks. I can't thank you all enough for all the time that you're spending on this. I think it's incredibly helpful.

I want to start. Our first item on the agenda is I want to fill you guys in a little bit on the comments to the temporary program certification rule that we distributed. Just so you understand the context, we did not talk about those in any detail in our last meeting. For those of you who remember, and it's been a couple of weeks, we didn't have a lot of time to review the text that was in the certification program rule on privacy and security and EHR modules, and so what I asked for folks to do was to send me some feedback before March 31st so that we could contribute to a discussion that the policy committee was going to have, which was a phone call last Monday because ultimately the recommendations that go to ONC do not come from the workgroups. They come from the policy committee. So the letter that you got is written as a workgroup letter to David Blumenthal, but in fact it needed, for it to have any real meaning at all, it needed to be blessed by the policy committee.

I did, in prefacing my remarks and introducing the letter, say that the letter did not come from the workgroup as a whole. That we did not have a chance to discuss it, and it instead reflected more anecdotal comments that had been submitted by workgroup members, and essentially the policy committee did agree with what we put forth, so the recommendation is a policy committee recommendation, not withstanding that from the letter it looks like it's a workgroup recommendation. I can understand why it looks that way. It in fact looks that way.

I just wanted folks to understand the context. I got a fair number of questions understandably from folks like where did this come from? I don't remember talking about this. So I wanted to make sure people understood the context and also much of what was in the temporary program rule for which comments are due to ONC by April 9th, which is the reason why we were on such a truncated time schedule. That's tomorrow. And again, they had to policy committee comments and not workgroup comments.

The permanent program rule comments of which there's remarkable level of overlap between the two are not due until May, and so I would like to reserve some time on our next call so that we can, as a workgroup, talk about whether and what comments we might want to make to the permanent program rule at that time and have a more complete discussion. Does anybody have any questions about that, concerns, comments?

Paul Egerman – eScription – CEO
This is Paul Egerman. I just want to say first, this is a very important process because it's one thing to make general recommendations about privacy, but what's in the NPRM about certification is sort of like where the rubber is meeting the road is saying what's really going to happen in terms of how it's going to get tested. So it's very important to look into that. I think it's excellent to do one more path on this, and make sure we've got it all right prior to May. I think it would be May 8th would be the deadline probably, either 8th or 9th for the comments on the final program.

Deven McGraw - Center for Democracy & Technology – Director
Right.

Gayle Harrell – Florida – Former State Legislator

Ditto from Gayle.

Deven McGraw - Center for Democracy & Technology – Director
Terrific. We will do that then. The next, before we move to the – the next item in the agenda is, and I had framed this on the agenda as finalizing our stage one direct or direct stage one exchange recommendation for which I re-circulated the paper that we've been working on for a couple of workgroup calls now. And for folks, from members of the public, what I'm referring to is the document in the download section that's recommendation on direct exchange. I've had some subsequent discussions with staff at ONC.

And we've been thinking that rather than submit these recommendations as a final direct exchange recommendation that would get presented, for example, at the April 21st meeting, and then subsequently what our recommendation might be on what I'm calling for shorthand non-direct exchange, that the better course of action would be to submit the two together as a package that really then deals with what we think about this consent issue and in the various iterations, whether it's direct one-to-one exchange or exchange through some intermediary HIE network that has certain characteristics, which we're going to talk about, we're going to begin talking about today, but I can't imagine that we will finish that discussion today, and it'll take us some time to tease through this. And so, I want to get some workgroup feedback on the idea of instead of submitting these recommendations as two distinct recommendations, instead to ultimately package them as a whole and use the meeting on April 21st to report to the policy committee on what we're doing at a high level and start to get some feedback from them, which we can then incorporate into the discussions that we're continuing to have on this issue.

One distinct advantage is that because I think it's going to be a struggle for us to define what types of intermediaries trigger the need for some type of consumer choice to be applied, that we might want to keep that direct exchange recommendation in our hip pocket so that as we're sort of reaching some conclusions as a workgroup about when we want to require some additional level of consumer choice beyond what's already required in law, we've sort of got kind of a full complement to present versus presenting it piece meal, but I'd love to get feedback from you all on this.

Gayle Harrell – Florida – Former State Legislator
This is Gayle. I think that's an excellent idea. I'm still a little uncertain about our recommendation on the direct exchange, when it goes through an HIE or RHIO. I think that whole thing still is up in the air. Even though it is only going for transport … me very concerned. So I think doing it as a package with direct exchange, entity-to-entity, direct is one thing. The minute it starts going off, I would rather have a whole concept laid out before we go preventing anything.

Terri Shaw – Children's Partnership – Deputy Director
Yes. This is Terri Shaw. I would agree. And also in part because I think it's inevitable that as we work through the non-direct policy issues we will want to refine the direct policy for this group.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
I have a question. This is Dixie.

Deven McGraw - Center for Democracy & Technology – Director
Sure.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences

I think, you know, a couple of people have pointed out that direct, NHIN Direct is not really direct. So I would like to know who is responsible for defining what we mean by direct exchange versus not direct exchange.

Joy Pritts – ONC – Chief Privacy Officer
Dixie, this is Joy. I think we could get to that, the substance in a minute or so, but right now I think that we'd like to focus on the process by which the recommendations will be submitted.

Deven McGraw - Center for Democracy & Technology – Director
Yes. Dixie, I actually think it's a good question, and it just underscores why it's important for us to sort of present these as a packaged deal versus piece meal, which is, initially we had language in the recommendation on direct exchange as calling out NHIN Direct as one possible example, but it's not clear that there aren't intermediaries involved in NHIN direct. I think all of that is still being determined and scoped out. And so I think it's up to us to decide what we mean when we say direct exchange isn't going to require anything beyond, at least from a consent perspective, what's already required in law, and to set out what our assumptions are in that regard. Consequently, when we determine what, if anything, does require additional consumer choice, what are the factors that trigger that. Does that make sense?

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
Yes. From a process perspective, I totally agree with you that they belong together.

John Houston – Univ. Pittsburgh Medical Center – VP, Privacy & Info Security
This is John Houston. The only concern I would have about leaving recommendations un-presented is that since these meetings are open to the public, would there be any possibility that the HIT policy committee would be asked about recommendations that we've made that they wouldn't know about simply because they haven't been presented to them yet. Yet we've sort of at least philosophically decided that they are recommendations that we're going to make.

Paul Egerman – eScription – CEO
This is Paul Egerman. I think that's a good comment, John. But the process that I think is being discussed is actually a process we've used before, so we did this with, like, patient safety where the last time I said here's what we're thinking about, and told people what it was we were thinking about without formally saying this is what we want to do. And so, that's what I understood would be happening next would be that the policy committee would be updated, and so they would know, this is where we are on direct exchange, and people that could provide better feedback, but we're not clearly going to ask for their approval on anything until we get the whole package together. I think that responds to what you're asking about. I'm not sure, but I think it does.

Deven McGraw - Center for Democracy & Technology – Director
Yes. Inevitably, folks are aware that this is what we're talking about. But we will be very careful. I think Paul is right. Rachel and I will be very careful about how we frame this to the policy committee, which is, here's what we've been considering. We would love your feedback. We'll get back to you with more firm recommendations when we're ready.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
I'd like to reiterate that our recommendation has a great deal more impact and it becomes then this is what we're thinking about.

Deven McGraw - Center for Democracy & Technology – Director
Yes.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
Giving the update, as Paul said, is a valid and important thing to do.

John Houston – Univ. Pittsburgh Medical Center – VP, Privacy & Info Security
I don't disagree. I just want to make sure that the policy committee isn't – if things aren't getting out of synch, and that's fine, as Paul indicated.

Deven McGraw - Center for Democracy & Technology – Director
Yes. Those of us who are on the policy committee will have to do our best to make sure that it doesn't vere off into, you know, that these conversations don't get interpreted to be something that they're not.

John Houston – Univ. Pittsburgh Medical Center – VP, Privacy & Info Security
Right.

Kathleen Connor – Microsoft Health Solutions – Principal Program Manager
Deven, this is Kathleen.

Deven McGraw - Center for Democracy & Technology – Director
Yes.

Kathleen Connor – Microsoft Health Solutions – Principal Program Manager
I support this approach, but there's a piece of it that I'd also like to see looked at across both the direct and the federated or NHIN, full NHIN kind of exchange, and that's the question of what are the transactions that are being considered. In the talking points that you've sent out … we've been using this to discuss this previously. We talk about exchange that occurs today. Now the exchanges that occur today, some are covered under HIPAA. Some are not. Then there are some new, electronic transactions that are being asked of providers. For example, sending preventative information to patients, sending patients copies of their records, providing them access, which could be considered a transmission of some sort, and I know that HIPAA does cover a patient's request for getting copies of their records, but these are not typical transactions today electronically, and so I think we need to also be looking at the full array of exchanges that we're considering before we say for sure that what's required under current law. I'm hoping you'll help me reframe that.

Deven McGraw - Center for Democracy & Technology – Director
I think I understand what you mean. One thing to keep in mind is that right now as the direct exchange recommendation is currently written, it's limited to the transactions that are required to meet the stage one criteria for meaningful use. We acknowledged that in most cases the recipient of data that might be disclosed under stage one would be another HIPAA covered entity, but there would be other circumstances where it would not, and the public health authority who receives reports pursuant to stage one meaningful use is one of them. And another area is if the patient asks for information that they're getting a copy of, either because they ask for it, or because the doctor is sending to them as part of their obligation under meaningful use to send the treatment reminder, for example.

That that PHR might in fact not be covered, but one thing that we should keep in mind that we, at least I have assumed, and the other lawyers on the phone can correct me if I'm wrong is that in all of those cases under stage one where the data is going to the patient, the patient has either expressly asked for it or has consented, I don't know authorized, because that's a different term under HIPAA that requires a fairly detailed authorization to be completed, but the patient has to identify how they want to receive the reminders, for example, and where they want to receive them before anything gets sent.

I have presumed that in fact in those transactions, consent is already a part of the law for those stage one transactions and that, again, since our direct recommendation is about what additional consent beyond what's already required in current law is necessary for stage one versus other issues such as secure transport, for example, that might arise with respect to some of the transactions under meaningful use.

Kathleen Connor – Microsoft Health Solutions – Principal Program Manager
I still have a concern about that because, just because a provider has given, and we're not clear yet what is meant by patient preference. It could be that the patient can prefer that the information be sent to a PHR, but that the provider can decide what PHR. Or it may be that they can state, I want it in this PHR, and the provider can say, yes, I'll send it there. And I'll also put it in the one that's attached to my EHR. There's some ambiguity there that I think would be best if we talked about all the possible scenarios or wait until we see what the final result is from the final rule.

Paul Egerman – eScription – CEO
Deven, as I listen to some of these comments, there seems to be a little bit of a common theme, which is people, I think, need in the documents rule a bit more clarity about this is what's the meaning of direct peer-to-peer. What are the circumstances that we're talking about consent? At least that's what I'm hearing is a common comment.

Deven McGraw - Center for Democracy & Technology – Director
I can certainly try to flush that out in some more detail, and I have more time to do that since we're not trying to present this. And I appreciate that, and I know Kathleen, a couple of weeks ago, you sent an e-mail to the workgroup where you identified some areas of uncertainty. So with your permission, I'll sort of use those as a jumping off point to try to provide some clarity about what we understand to be the rule and how our – for example, what I might consider, what I'm thinking about adding to the document is a statement such as we assume that the patient has the choice about where the data is sent.

Kathleen Connor – Microsoft Health Solutions – Principal Program Manager
Yes. I think that would be a good approach. Thank you.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
Yes. That's good.

Terri Shaw – Children's Partnership – Deputy Director
This is Terri Shaw. Perhaps another way is, not to use the use case term too much, but if we can provide a couple different scenarios that might help to illustrate how we think this would be applied, that might be useful as well.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
Yes, that would be.

Deven McGraw - Center for Democracy & Technology – Director
Good point, very good point.

Terri Shaw – Children's Partnership – Deputy Director
And maybe say the ones that we explicitly don't think fall into the scenario like sending copies of records to PHRs that are not the ones the consumer chose.

Deven McGraw - Center for Democracy & Technology – Director

Let me see what I can do on that one to make it more clear. It is the case, I think, that a lot of us have had in our minds, some built in assumptions about how this would work that have given us the level of comfort that we have so far expressed with respect to direct exchange. It can only be helpful to make sure that those assumptions are very clear and that we're all on the same page.

Mike DeCarlo – BlueCross BlueShield
Deven, this is Mike DeCarlo. Is this concept of the individual making the choice as to where he wants the information sent going to be – is it not going to be affected by whatever regulation is written to implement the HITECH requirement that the individual now has the right to an e-copy of their EHR data?

Deven McGraw - Center for Democracy & Technology – Director
Yes. No, absolutely. And so I think that we're going to have to create the set of assumptions and scenarios under which our particular recommendation, which at least as it stands now, says when it's direct exchange for stage one, current law provides a sufficient level of consent, and we're not advocating for any more than that, and that's based on the following, but you have to recognize that there's still outstanding – you know, we're not sure yet how the Office of Civil Rights is going to interpret the new, electronic access.

Mike DeCarlo – BlueCross BlueShield
These would be exchanges, but … entities that are not necessarily covered under the current HIPAA TPO requirements, if I'm following the conversation.

Deven McGraw - Center for Democracy & Technology – Director
Yes. I mean, in some cases that would be the case.

Mike DeCarlo – BlueCross BlueShield
Yes. Okay.

Deven McGraw - Center for Democracy & Technology – Director
Again, we're looking. We have, at least to date, been speaking of the set of transactions that are called for in stage one of meaningful use.

Mike DeCarlo – BlueCross BlueShield
Thank you.

Marianna Bledsoe – NIH – Deputy Associate Director
This is Marianna. Are we talking about, in this recommendation, one-to-one exchange of identifiable data?

Deven McGraw - Center for Democracy & Technology – Director
Yes because that's stage one.

Marianna Bledsoe – NIH – Deputy Associate Director
I think it would be helpful just to clarify that.

Deven McGraw - Center for Democracy & Technology – Director
I guess, let me step back then. Some of the quality reporting that occurs under the stage one meaningful use criteria is, while maybe not de-identified per HIPAA standards, it might also not be fully identifiable. Is there something, Marianna, that you're seeing? Again, we're talking about what has to happen for stage

one, and that also includes public health reporting requirements, which may or may not be in identifiable form, depending on the particulr state law.

Marianna Bledsoe – NIH – Deputy Associate Director
What I'm getting at is that under the HIPAA privacy rule, there are exchanges that can occur for reserch purposes without consent. For example….

Deven McGraw - Center for Democracy & Technology – Director
But are any of those in stage one of meaningful use?

Marianna Bledsoe – NIH – Deputy Associate Director
There is one, and there's some ambiguity in this about one of the stage one objectives of providing lists of patients for X, Y, and Z, and it includes research as one of those items. I don't remember exactly how it's framed right now. Yes, that is the one objective where research is specifically mentioned.

Deven McGraw - Center for Democracy & Technology – Director
I definitely want to look into that one.

Marianna Bledsoe – NIH – Deputy Associate Director
Right, because I think, you know, again, I think this gets back to providing a little bit more clarity around what kinds of exchanges we're talking about and for what purposes.

Deven McGraw - Center for Democracy & Technology – Director
Right. I mean, keeping in mind that at least the recommendation, as it stands, is current law applies. Now if consent were required in that particular research context, it still would be.

Marianna Bledsoe – NIH – Deputy Associate Director
So this is not going beyond the current requirements.

Deven McGraw - Center for Democracy & Technology – Director
Not so far vis-à-vis direct exchange for stage one. But I still, if you can send me the particular criteria you're talking about, that would be helpful. We want to make sure that we're clear on that.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
Would you mind sending that to everybody on the workgroup?

Deven McGraw - Center for Democracy & Technology – Director
Yes. Marianna, that's fine.

Marianna Bledsoe – NIH – Deputy Associate Director
Sure. I will.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
Thank you.

Deven McGraw - Center for Democracy & Technology – Director
Any other questions before we set the direct recommendation to the side? Not finalized, but for back pocket, and move on to the discussion about consumer choice and state HIEs and other "networks" with an understanding that we don't have good, common terminology here yet.

Peter Basch – MedStar Health – Medical Director
Deven, it's Peter. I have one question.

Deven McGraw - Center for Democracy & Technology – Director
Sure.

Peter Basch – MedStar Health – Medical Director
It's kind of a side question. Is the term NHIN Direct as opposed to direct exchange something that is now considered set in stone, or is that evolving as well?

Deven McGraw - Center for Democracy & Technology – Director
No, that's evolving, and it's one of the reasons why I took out or I thought I did.

Peter Basch – MedStar Health – Medical Director
You might have. It's just….

Deven McGraw - Center for Democracy & Technology – Director
…NHIN Direct reference from the recommendation. I think at least this recommendation, as it is today, is about direct one-to-one exchange.

Peter Basch – MedStar Health – Medical Director
No, I got it. I just wanted to make sure….

Deven McGraw - Center for Democracy & Technology – Director
Yes, and so we're not. Initially we had talked about NHIN Direct as being an example of this, and then I heard from a number of people that in fact NHIN Direct is going to be including intermediaries, at least in some cases. It's not entirely clear what role those intermediaries will play and what access they'll have to data, and so I think, given that that's the very set of issues that I think Gayle really put her finger on earlier in the call that make a lot of people nervous. At least for now, I don't think we can say NHIN Direct doesn't require anything additional.

Peter Basch – MedStar Health – Medical Director
No, and that wasn't my point. My point was, if we were referring to direct exchange synonymously with NHIN Direct, and you clarified that. Thank you.

Deven McGraw - Center for Democracy & Technology – Director
Yes. Not right now.

Gayle Harrell – Florida – Former State Legislator
Deven, this is Gayle.

Peter Basch – MedStar Health – Medical Director
Probably never.

Deven McGraw - Center for Democracy & Technology – Director
Maybe not ever. Right. Hello, Gayle.

Gayle Harrell – Florida – Former State Legislator
Hello. One thing, you know, when you're thinking of terminology, we're going to have to come up with a term that is clear and concise to everyone because this gets very, very cloudy. And people have different

interpretations, so I think finding the right word is going to be extremely important for something that is non-direct. And I don't know that non-direct is the appropriate term.

Deven McGraw - Center for Democracy & Technology – Director
Yes.

Gayle Harrell – Florida – Former State Legislator
You know, I don't know whether it's facilitated, non-direct, something, but I think that the terminology needs to be concise.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
I agree, and I think that we should avoid the term "direct" entirely because people do, we all, including us, you know, you tend to relate it to NHIN Direct. And I think that we should come up with our term and explicitly define it.

Gayle Harrell – Florida – Former State Legislator
Correct. I agree with you. Absolutely, Dixie.

Marianna Bledsoe – NIH – Deputy Associate Director
This is Marianna. Speaking of terminology, I think we're going to also need a very clear definition of an HIE and RHIO. I think we have some very broad definitions, but when we're talking about networks, I think we have to get a little bit more specific--

Deven McGraw - Center for Democracy & Technology – Director
Absolutely.

Marianna Bledsoe – NIH – Deputy Associate Director
--because there are things like research networks that collect and data repositories that collect data for purposes of research. And so I was struggling to try to figure out what exactly is an HIE.

Deven McGraw - Center for Democracy & Technology – Director
Yes, well, join the club.

Marianna Bledsoe – NIH – Deputy Associate Director
I thought I was missing something.

Deven McGraw - Center for Democracy & Technology – Director
No, you're not missing something. In some respects, in order to create some documents to generate conversation, I have to sort of pick some defaults, and there are placeholders. For now, let's just say that we're moving into a phase where leaving one-to-one exchange and moving into mediated or facilitated exchange where there's something in the middle that is doing more than just the transport.

Judy Faulkner – Epic Systems – Founder
This is Judy, and one possible terminology you could think of is repository based exchange because that is the technology for how they do it.

Kathleen Connor – Microsoft Health Solutions – Principal Program Manager
This is Kathleen. That is one type. I would agree, Judy, one type of the non-point-to-point, unmediated … exchange.

M
But it's not the only type.

Kathleen Connor – Microsoft Health Solutions – Principal Program Manager
I'm wondering if we could possibly maybe work on this, you know, through e-mail. We could try to see if everyone can come up with something.

M
I agree.

Deven McGraw - Center for Democracy & Technology – Director
Yes, yes. No, I definitely don't want to spend any more time trying to find a good term, and instead, get to the meat of what are the characteristics of non-point-to-point or mediated exchange that we might want to apply a higher level of consumer choice to.

Kathleen Connor – Microsoft Health Solutions – Principal Program Manager
This is Kathleen.

Deven McGraw - Center for Democracy & Technology – Director
Kathleen first, then Paul.

Kathleen Connor – Microsoft Health Solutions – Principal Program Manager
Okay. Sorry.

Joyce DuBow – AARP Public Policy Institute – Associate Director
And then Joyce, please.

Deven McGraw - Center for Democracy & Technology – Director
Joyce, okay. Absolutely.

Kathleen Connor – Microsoft Health Solutions – Principal Program Manager
All I want to say is to Judy's point. She talked about there are several types in this set, and that's what, and I think you've pulled out a lot of the criteria in your papers. But aligning the specific ones, the specific characteristics to the types is probably the work that needs to be done. There's not just one kind of mediated exchange.

Deven McGraw - Center for Democracy & Technology – Director
Right.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
And it's not a bad idea.

Deven McGraw - Center for Democracy & Technology – Director
Wait. Paul is next, Dixie.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
I'm sorry.

Deven McGraw - Center for Democracy & Technology – Director
That's okay. I put you in the queue.

Paul Egerman – eScription – CEO
This is Paul. My comment is that perhaps we shouldn't view it as only two things, which is direct and everything else, because I listened to what Judy said, and repository is a major aspects, and so I'm not sure it's necessarily the right word, but you could have direct. You could have repository, and maybe there's one or two other things that we also define. In other words, it doesn't have to be two groups. It could be three or four.

Deven McGraw - Center for Democracy & Technology – Director
Yes.

Paul Egerman – eScription – CEO
Because I think repository is a major category. I think what Judy raised is a major category. It has its own set of privacy issues. I mean, there's privacy, but there's also security. I mean, there's consent, then there's privacy, then there's security. And whatever framework we put together, we want to be able to address all of the issues, not just consent with.

Deven McGraw - Center for Democracy & Technology – Director
That's right.

Paul Egerman – eScription – CEO
And so, you know, if you define repository the way Judy just suggested and say that that's a broad category that describes a lot of things, maybe not everything, but describes a lot of the things, well, that might be a good thing for us to be able to identify.

Marianna Bledsoe – NIH – Deputy Associate Director
This is Marianna.

Deven McGraw - Center for Democracy & Technology – Director
Wait. I'm sorry. Joyce is next.

Joyce DuBow – AARP Public Policy Institute – Associate Director
I just have a very, very generic observation, and that is that I think we need to decide who has to understand this. There's a lot of inside baseball terminology here. If this is only for the policy committee, that's one thing. If it's for the public to understand this infrastructure, what we're talking about, I think we need to have some kind of glossary that explains what we're saying. Even the ones who want exchange may be complicated. I don't mean to make it more complicated for our discussion, but I really don't think people are going to know what you're talking about here. I think it's an issue.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
I see the….

Deven McGraw - Center for Democracy & Technology – Director
Yes. No, Joyce. I'm just laughing because I'm sharing your frustration, and I think our audience is really both. I want to pick up Dixie, and then Marianna, and then try to get some dialog on characteristics going. Dixie?

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
Yes. Yes, what I was going to say, and I didn't mean to blurt it out, but it just occurred to me as you were talking. Perhaps the way we evolve, instead of starting by coming up with these complex definitions,

maybe we explore circumstances under which we believe consent is required and, out of that, our definition of direct and not direct or whatever we're coming up with might emerge.

Deven McGraw - Center for Democracy & Technology – Director
You mean is required or should be required or both?

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
Both, both, but our real focus shouldn't really be on the complexity of the architecture, etc. Our real concern is when is and should the individual, the consumer's consent be required. And I think that that should be our focus.

Deven McGraw - Center for Democracy & Technology – Director
Yes. Marianna?

Marianna Bledsoe – NIH – Deputy Associate Director
Yes, I'd like to echo that, and actually build upon that. Where I was thinking about, the way I was thinking about this is that, you know, I think it would be useful to figure out sort of what kinds of, you know, what kinds of scenarios might provide additional risk. I mean, isn't that why we would ask? I mean, so why would we ask for consent over and above what's already required?

Deven McGraw - Center for Democracy & Technology – Director
Right.

Marianna Bledsoe – NIH – Deputy Associate Director
It's sort of to take a step back and use that as a starting point because I think consent won't do everything in this model, and we should not expect consent to do everything. Consent lets people know what's going on, but it certainly is not a substitute for good privacy and security protections that are in place, and if you work on the good privacy and security, then perhaps maybe you can take a more liberal approach with regard to consent.

Deven McGraw - Center for Democracy & Technology – Director
Right.

Gayle Harrell – Florida – Former State Legislator
This is Gayle. I'd like to add to that.

Deven McGraw - Center for Democracy & Technology – Director
Go ahead, Gayle.

Gayle Harrell – Florida – Former State Legislator
I think we have got to build trust with the public. And I'm on my soapbox, I know, and people make comments about my soapbox. But, you know, I think, unless you really define this and you make sure that the public understands, and that whole comment about who are we talking to. We're talking to the public.

Deven McGraw - Center for Democracy & Technology – Director
Right.

Gayle Harrell – Florida – Former State Legislator
We are talking….

Deven McGraw - Center for Democracy & Technology – Director
Ultimately, we are talking to the public.

Gayle Harrell – Florida – Former State Legislator
And we have got to make sure, and I like the idea of saying, when do we think that extra degree? When do we need consent, other than that direct, one-to-one exchange? I think that's a good way to start. But always, always remembering that unless we can make the public comfortable with what we're doing, we're totally missing the mark.

Joyce DuBow – AARP Public Policy Institute – Associate Director
That was my point. Thank you.

Marianna Bledsoe – NIH – Deputy Associate Director
And I'd like to make one more comment to that. This is Marianna again, and in reading through some of these documents, one of the issues, and clearly gets to why people are so concerned about this is that what we want to protect is the misuse of information in discrimination and employment and all of that. We haven't fixed that, but we need to think about how best to secure that information in a way that will allow data to be shared for legitimate purposes, including treatment, research, public health, and so on, without unnecessarily restricting the flow of that information.

Deven McGraw - Center for Democracy & Technology – Director
Right. I think that I started to sketch out some framing points in this document, and for folks, members of the public, this is one of the other downloads that's available via the Web. It's called HIE Network Consent with full admission that those terms are not very well defined. It was, you know, at some point you need shorthand for the title of a document, and that was going to have to suffice for now. But for folks who want to see that, that's where you can get it.

And I started with a set of framing points of which, you know, acknowledging that consent is only one issue that would need to be resolved for exchange and for the public to trust exchange. It's an important one, but it's not the one and only. And we have, in framing points in the past, made the point that in fact, you know, to hit this right means that we have developed a set of policies and practices and protocols that in fact do increase public trust, but also get us the benefits of health IT and all of its various iterations, and we can certainly add something to that.

I do think that it's important for people to understand what is at the baseline of the recommendations that we make, and I don't think there's any disagreement about that. I think that I really do, though, now want to get us to a more substantive discussion of what you guys had started to frame as what are the aspects of mediated exchange that suggest the need for giving consumers additional rights as to whether their data is involved.

Kathleen Connor – Microsoft Health Solutions – Principal Program Manager
This is Kathleen. I'd like to suggest that we start with what it is that makes us comfortable as a group, it seems, about a point-to-point exchange only having to meet what's already required in the law.

Deven McGraw - Center for Democracy & Technology – Director
Okay.

Kathleen Connor – Microsoft Health Solutions – Principal Program Manager

And whatever it is that makes us comfortable, what past that is going to make us uncomfortable? And I would suggest just for starters, usually where the treatment relationship is established and understood by the consumer and the idea that information would be out in a repository or available through some mediated exchange, maybe for treatment, but it's not treatment that I'm particularly aware of or anticipating.

For example, an HIE might have a collection of medication history provided or accessible through a pharmacy intermediary. And they have it in this HIE because perhaps in the past had a prescription written for me by a provider in that exchange. But I know longer see that provider. I may not want to see any other providers in that who are participating in that exchange. So is that a point at which the treatment relationship that had previously been sort of understood and accepted, I think, by most people, starting to break down, and what is the line in which treatment relationships start to break down in these mediated environments? That's a place to me.

Rachel Block – New York eHealth Collaborative – Executive Director
Deven, this is Rachel. I guess, just a comment on that and building off of a little bit of our earlier conversation as well. I think we have to be very careful about some of the assumptions that we're making about how much individuals know about the medical professionals with whom they either are or may have interactions with. In a circumstance of a referral, you may know that there is a site that you are going to. You may know that that site is affiliated with a particular institution. I will bet you that in 99% of the time you do not know the name of the individual practitioner that you will be seeing at that site in advance. So I just want to be careful about some of the assumptions that we're making in terms of real life, day-to-day, how do these kinds of referral arrangements actually work, and how much the consumer actually knows. I just don't want to build in too many restrictions to things that happen today without any barriers to information exchange. And just because we're using electronic means doesn't mean that we should put more barriers into them.

John Houston – Univ. Pittsburgh Medical Center – VP, Privacy & Info Security
This is John Houston. I would….

Kathleen Connor – Microsoft Health Solutions – Principal Program Manager
That is what I was talking about. I mean, trying to explore those areas and find out where the area of discomfort might be. I wasn't asserting one.

Deven McGraw - Center for Democracy & Technology – Director
Okay. John, go ahead.

John Houston – Univ. Pittsburgh Medical Center – VP, Privacy & Info Security
Yes. I just wanted to add to that slightly. This may sound slightly cynical, but I think, at the end of the day, often patients don't necessarily know what they want, and so we have to try to be practical and pragmatic about this because I think, at the end of the day, often patients will express a desire for great control over their data, but then expect that data to be very widely available as necessary for their treatment. And so, you know, I just, I want to make, I think we have to look at not the theoretical, but the practical implications of what we put into place.

Deven McGraw - Center for Democracy & Technology – Director
Yes. I think that's absolutely true. Kathleen, I actually like, with Rachel and John's comments well understood that in fact we are always dealing with a population without full knowledge of the way things happen today. I do like your idea of starting with, what is it. What was it that at least to date has made us comfortable with the idea that in point-to-point, we don't think that at least for the stage one of meaningful

use, we don't think that additional consent beyond what's already in the law. We're not trying to trump existing law here, necessarily is required. But we stopped there, and it's sort of the next step.

I know, for myself, I have characterized it as more of a digitization of what happens or should happen today, which is, you know, the data sharing from one provider to another where the data comes from the provider who has traditional responsibilities and legal obligations over it, sending it out to another provider because she knows that that other provider will need it because she's sending her patient over there. So it gets sent, and that, you know, there's a comfort level there. There's not something in between that, in the process of transporting that data, looks at it or stores it and has independent rights to it in some way, shape, or form.

Gayle Harrell – Florida – Former State Legislator
That trusted relationships.

Paul Egerman – eScription – CEO
Yes.

Deven McGraw - Center for Democracy & Technology – Director
Right. And it is. I think you're right, Gayle. It's based on that people generally trust their doctors with their data.

Paul Egerman – eScription – CEO
This is Paul Egerman. I agree with that. What makes me comfortable with the direct exchange is I view this almost like instead of thinking about zeros and ones in exchange of data. If you thought about it like, gee, my physician referred me to a specialist. And the specialist called my primary physician and asked a question, I'd expect the primary physician to answer it because I trust him, and I expect him to answer it. But it's like the trusted relationship that you have with the physician that he or she is deciding what information to send out, and is doing that as part of the course of treatment.

The part that makes at least me uncomfortable was the idea of intermediaries that have repository as, well, now there's a copy of the data, and who has that data, and who are they anyway. And what might happen to that data once it's there? I don't know who those people are, but I know who my physician is.

John Blair – Tacanic IPA – President & CEO
Deven, this is John Blair. It sounds to me like the clear theme that's coming out is if the data, during transport, is retained or something else is done with it other than the transport.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
Deven, this is Dixie. I think it's more the primary versus secondary because if they put it in a repository, but that repository is still, for example, Kaiser. You know, an individual location puts the data into a repository that's shared throughout Kaiser. That's still a primary use of the data. But if the data are being used for secondary purposes of any kind, I think that's when the question of consent arises.

John Blair – Tacanic IPA – President & CEO
But, Dixie, that is still within one provider at Kaiser.

Deven McGraw - Center for Democracy & Technology – Director
Yes.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences

Yes. But I would say, even if it were more of a traditional or an IDN, IDNs often are multiple providers that are not all the same company.

John Blair – Tacanic IPA – President & CEO
Well, but that's….

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
But as long as it's a repository where the data are still being used only to make me well and keep me well, I'm not concerned about it. But the question or concern arises on secondary uses of it like uses for marketing or research or quality measures or anything that's not what I care about, you know. My health is what I primarily care about, and any other uses, I think, then the question has to be asked.

Judy Faulkner – Epic Systems – Founder
This is Judy, and I think that there are two things. One is….

John Blair – Tacanic IPA – President & CEO
Well, I don't. I mean … that concerns me….

Deven McGraw - Center for Democracy & Technology – Director
Hold on. Let me let John respond.

Judy Faulkner – Epic Systems – Founder
I'm sorry. Go ahead, John.

John Blair – Tacanic IPA – President & CEO
That confuses me because that's now talking about a repository within a covered entity.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
No, I don't mean that. I mean outside a covered entity but shared. Tenet Health, you know, Tenet Health has a number of hospitals that are Tenet Hospitals, but I guess, are Tenet Hospitals, that's multiple covered entities?

John Blair – Tacanic IPA – President & CEO
Right.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
Each one is a separate covered entity that they all happen to be owned by Tenet. You know, if they had a repository in Dallas where they put all their information from all those hospitals, I'd still not – I don't know. I don't know.

Kathleen Connor – Microsoft Health Solutions – Principal Program Manager
Deven, will you put me in the queue? This is Kathleen.

Deven McGraw - Center for Democracy & Technology – Director
Yes. You're after Judy.

Kathleen Connor – Microsoft Health Solutions – Principal Program Manager
Thank you.

Marianna Bledsoe – NIH – Deputy Associate Director

And put me in the queue too. This is Marianna.

Deven McGraw - Center for Democracy & Technology – Director
Okay. Thanks, Marianna.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
I think it's really … you know, how far secondary use versus primary use. I really do.

Deven McGraw - Center for Democracy & Technology – Director
I think we should continue to explore that. Judy, go ahead.

Judy Faulkner – Epic Systems – Founder
Yes. I think, Deven, I think folks are right on the word repository isn't right. If it's going to be – I just send you an e-mail on this, Deven. A and not A mathematically … then it's got to be direct and indirect mathematically. The other point that I was thinking of though is I think, as we figure all this out, we shouldn't be thinking of going forward. We should be thinking of going backwards. And that we shouldn't be thinking of what's next and how it works, but let's imagine the world 10 or 20 years from now when this is all accepted.

And when you go to the doctor's office, you wouldn't dream of your information not being there, so then how do we get to that state, and then what kind of privacy considerations and other considerations do we put in place to make that state the right state? But I think part of the problem we have right now is going from here to the next step is harder from going to the end stage backwards.

Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO
Deven, it's Paul. Can I get in the queue too, please?

Deven McGraw - Center for Democracy & Technology – Director
Sure can. Kathleen, you're up next.

Kathleen Connor – Microsoft Health Solutions – Principal Program Manager
I was looking at the definitions in HIPAA of a couple of terms that I think might be helpful here. One is direct treatment relation, indirect treatment relationship, which would speak to what Rachel was talking about, and then the definition of treatment itself. If you take all those pieces together, those are the things that make me comfortable when I go to the doctor's office and sign the notes of privacy practices that this provider is going to be basically adhering to those parameters that we have a direct relationship or that they may be able to send information for an indirect relationship, and it's for purposes of treatment, as defined in HIPAA, which is very clearly not secondary, and it's clearly not sort of borderline between treatment and secondary uses. So we might want to look at that as an approach to capturing this idea of comfortable, trusted relationships that we have to date. Thank you.

Deven McGraw - Center for Democracy & Technology – Director
Okay. Marianna, and then Paul.

Marianna Bledsoe – NIH – Deputy Associate Director
Yes. You know, there seems to me that there are two fundamental issues here. One is the risk issue, and I think maybe there's, perhaps there's some discomfort in going from a one-to-one direct exchange to something that stores and holds data. And I think that some of that discomfort can perhaps be mediated by putting in additional privacy protections, governance, and oversight, perhaps through criteria that could even be built into meaningful use in certain scenarios. And the other issue is autonomy, and that's where

we get into, I think, the secondary use issues and where I think consent comes in. Also, a fundamental piece of this, and I don't think we can talk about consent without also talking about public education. What do people understand about what happens to their data?

Deven McGraw - Center for Democracy & Technology – Director
Right. Paul?

Adam Green – OCR
This is Adam Green. Could you add me to the queue?

Deven McGraw - Center for Democracy & Technology – Director
Yes. You're after Paul Tang.

Gayle Harrell – Florida – Former State Legislator
And Gayle Harrell.

Deven McGraw - Center for Democracy & Technology – Director
And you're after Adam.

Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO
Thanks, Deven. And I'm sorry I joined late. Maybe I'll try to word it slightly differently, and try to capture. I think we're all struggling for how do we know when people are comfortable versus not, and our goal being to create a trust and trustworthy system. I think one concept that may be a label that can be applied to the concept is expectations, and I think people have said that. Maybe not with those words, but trust means meeting the expectations of an individual patient. On the contrast, mistrust gets created when you violate my expectations.

Now everybody has their own personal expectations, but there probably is a generally held expectation. And the reason that may be important is because when we classify it by only direct or only primary and secondary uses of data, we come up with all kinds of exceptions like public health and research, etc. So I'm wondering whether the public mind is this concept of trust, and maybe one way to characterize it is meeting expectations. If that's a way of characterizing what makes people comfortable in general, maybe we go after policies that meet people's expectations and model practices that describe, that implement policies.

What's an example? If we had model practices that we're able to enumerate the appropriate and lawful uses of data that meet people's expectations, that would be transparency, and it would also be a way to characterize and educate people on how your data is used. To the extent that becomes vetted or endorsed or modeled, then that can eventually evolve into a model without being a mandate, a model of privacy practices. And when you post that on the Web, we get to enforce it through FCC. I'm sort of going way to the end goal and backing up along the way. But I guess I'm trying to find the unifying concept that we could describe and explicitly enumerate that would capture what makes people comfortable, i.e. what makes people trust this system.

Expectation might be more of the word than primary/secondary. So the referral meets that test. I understand public health and bioterrorism meets that test. I understand clinical research. Most people do. That meets it, those kinds of things. Anyway, I throw that out.

Joyce DuBow – AARP Public Policy Institute – Associate Director

Can I respond to just that point? This is Joyce. The problem is that they don't, the expectations don't understand the scope, Paul. And so the issues around collecting data for quality improvement, for example, is not understood. And I think we could extend that concept of expectations too far if we don't take into account that the public doesn't understand the full scope or the full potential for how these data could be used.

Mike DeCarlo – BlueCross BlueShield
Deven, can I respond to that because I do…?

Deven McGraw - Center for Democracy & Technology – Director
I'm sorry. I had folks in the queue, and I've got to be fair. Mike, you're after Gayle. Adam is next.

Adam Green - OCR
I think I have some similarities to what Paul was saying.

Deven McGraw - Center for Democracy & Technology – Director
Adam, can you introduce yourself to the workgroup? I don't know if everyone knows you.

Adam Green – OCR
Okay. I was recently with OGC over at HHS, the Office of General Council. I've recently moved over to Office for Civil Rights, so I'm now in that.

Deven McGraw - Center for Democracy & Technology – Director
Right, which has oversight over HIPAA.

Adam Green – OCR
Yes.

Deven McGraw - Center for Democracy & Technology – Director
Okay. Go ahead.

Adam Green – OCR
Similar to what Paul was saying, I'm wondering if there's kind of two boxes that could be created here. The first one that comes to mind is sort of an implicit consent similar to what he was saying with respect to expectations. I think if you look at a relatively unsophisticated patient, when they go to receive treatment, I think there's an implicit understanding by then that the doctor is going to, or whatever practitioner is going to use or disclose their information as necessary for treatment. And I think also there's an expectation that this is not going to be done pro bono, so there's implicit consent that there could be disclosures in order, as necessary, to receive payment.

There are some healthcare operations that may be in there too. Obviously you hear me talking from a HIPAA frame here. But I also appreciate the fact that the unsophisticated consumer will not understand some of these other areas such as quality improvement, so that is a potential constraint on this implicit consent model. I think the other box that we have to look at is kind of necessary for public good where legislatures have met and said, okay, we feel this is so important that consent may not be necessary.

And I don't think that's necessarily a broad area. I think there are areas like research that are for public good, but there's not necessarily a few that or not a universally held view that you don't need the patient's consent, even though it's for public good. I think there's only a fairly limited amount that would fall under the really necessary for public good.

Deven McGraw - Center for Democracy & Technology – Director
Right.

Adam Green – OCR
But that those models might work a bit better, as Paul has suggested, than trying to look at architectures and whether it's a single point-to-point or intermediaries involved, etc.

Deven McGraw - Center for Democracy & Technology – Director
Right. So I have Gayle and Mike in my queue, and then I'm going to reset the discussion because one thing that I don't want to have on the table, at least at this stage, is a rewrite of HIPAA. Essentially one could argue that these were all of the considerations that went into play when the privacy rule was enacted. What are people's expectations? To what extent is consent implied, etc.?

What I'd like for us to try to separate that discussion from one about vehicles for transporting data. This sort of intermediary facilitated transaction, and to what extent beyond what is somewhat settled in law do we think there ought to be additional consent? Just so you know what's coming, but I want to get to the comment. I want to get to Gayle, and then Mike DeCarlo, and then try to reposition this a little bit.

Gayle Harrell – Florida – Former State Legislator
Okay. Before we reposition … I just want to address a couple things, and I've got some real – I want to be a little bit more concrete. I think the expectations that patients have and things that we need to address, as we look at consent, basically come down to who, what, when, where, and why is my information going to go somewhere. And I need to be comfortable and know who it is and why I'm comfortable on the one-to-one, you know, point-to-point thing is because I know who my doctor is, and I know that he is sending me to somebody she knows and trusts.

Deven McGraw - Center for Democracy & Technology – Director
Right.

Gayle Harrell – Florida – Former State Legislator
What is going to be sent? I know what's going to be sent. I know that he's going to send whatever information he has on me in order to get my treatment and take care of me in that trusted relationship. Where is it going to go? I know it's not going to go somewhere out in the Ethernet. I know there's authentication. I know that there is perhaps encryption, or there's some way that where it's going is secure. So that makes me comfortable. Then why is it going? That's the basic reason we're doing this is because it is for treatment or payment. And I understand payment is important too. So who, what, where, and why are really the foundational aspects of what builds that trust for patients.

And when it comes to, well, there are some items that perhaps the public good is so necessary that we have to go without that consent. Those things are very publicly debated in legislature. That doesn't happen. And I can tell you, it doesn't happen willy-nilly. Been there. Done that. You know, it doesn't happen without a great deal of public debate and on all sides of that question.

W
Deven, this is….

Gayle Harrell – Florida – Former State Legislator
So I think we need to put all that into….

Deven McGraw - Center for Democracy & Technology – Director
…in my queue.

Terri Shaw – Children's Partnership – Deputy Director
Yes, this is Terri. Can I get in the queue too?

Deven McGraw - Center for Democracy & Technology – Director
Yes, you can. Mike?

Mike DeCarlo – BlueCross BlueShield
Yes. I'm glad Paul brought up the word expectation because it was rattling around in my head while this conversation was going on, and I had the same thought. A lot has been said, so I won't add to it. Simply to say that the comment was made that the expectation is limited because people don't know. People aren't aware what might happen beyond a certain point, be it for treatment or payment, etc.

But I think that comes back to the transparency issue. To the extent that we need to put into the recommendations the idea that the education or the public, to raise their level of expectation of what can be done with this information in the electronic environment would mitigate a lot of these concerns that we're trying to find technological solutions to for security. And, ultimately, the belief, my belief is that the security is only good as the willingness of the individuals manipulating the system to comply with the requirements. You can't keep people from misusing information unless they're willing to do it. So if you raise the public's expectation about what will happen with their information, it will only be those outliers that are truly detrimental to their interest that need to be protected in such a way that it becomes an impediment to the flow of information, as it should be.

Deven McGraw - Center for Democracy & Technology – Director
Right. Terri, Terri Shaw?

Terri Shaw – Children's Partnership – Deputy Director
Yes. I'm here. I want to applaud your caution to us, Deven, that we're not revisiting HIPAA in its entirety and privacy in its entirety, and that we're really, I think, needing to focus on that aspect of this form of exchange that causes us heartburn. And, to me, it's less about – what I'm hearing in the conversation and what resonates with me is that it's less about the purposes or the entities or the form of the transaction, and it's more about this notion of the person that I trust with my information and, in most cases, who we're talking about here is a provider, is now going to speed control over that information to somebody else, to some other entity with whom I do not have a direct trust relationship with.

And that, to me, is the crucial turning point here that raises a new set of concerns and heightens the privacy interest for the patient because somebody that they don't know, some entity that they don't know and have a relationship with will now be making those decisions on their behalf, potentially, on what information can be shared, with whom, and for what purposes. And so it's in that case that we would, I think, reasonably expect there to be some notion of consent or choice on the part of the patient to say, yes, I want you to be able to share my information with that third party or not.

And, to me, that comes up in the case where there is a repository that is a queriable by multiple entities for multiple purposes and/or where the provider themselves is making available information. They hold the information, but they're making it available on a queriable basis through this network or through multiple entities for multiple purposes without them themselves controlling which individual people for which individual purposes they're providing access. So that, to me, is the turning point where there's a seed of control from the covered entity that you have a relationship with to somebody else.

Deven McGraw - Center for Democracy & Technology – Director
Terri, I think you said that very well, and you captured something that I tried to get at in some of my bullets, and I think I was too technologically specific to be terribly relevant, this sort of notion of a patient lookup or a record locator service. I think, for me, what I have trouble, what probably gives me the most amount of heartburn is this notion that somebody can query my doctor's records and pull information out, whether it's directly from my provider or through an intermediary, without me and potentially even my doctor knowing and sort of having some control, the doctor having some control over that is partly what gives me heartburn.

I know in the past that I've characterized that as push and pull, and I'm trying not to do that because I understand that those are not accurate, the accurate ways to describe what I'm talking about, but that, to me, is something that is very different in this new environment that doesn't necessarily fit with patient expectations. And I would add the repository-based piece to that too.

I think, again, I'm not, you know, folks who heard me testify at the policy committee know that I take a dim view of just how protective consent can be from a privacy standpoint because people are all too willing to sign the paperwork because they don't necessarily fully understand what they're doing. But having said that, there is something that strikes me about building trust in this enterprise going forward that, for repository based or queriable type systems, that we might at least give people a right not to be included.

Kathleen Connor – Microsoft Health Solutions – Principal Program Manager
This is Kathleen. I think the term autonomy that someone mentioned is perfect. We captured the idea that I have an expectation of autonomy with respect to data disclosures … the trusted relationships that I have with my providers for treatment, payment, and operations, as they're … by current law.

Marianna Bledsoe – NIH – Deputy Associate Director
This is Marianna. I don't know if there's anybody else in the queue right now.

Deven McGraw - Center for Democracy & Technology – Director
No, you're good. Thanks … jump in. If I'm not interrupting people, there's no queue. Thanks, Marianna.

Marianna Bledsoe – NIH – Deputy Associate Director
Yes. I think what we're dealing here with is sort of, you know, a wide variety of concepts from building trust and transparency by making clear through public education of patients how their data is going to be used and protected. Consent, I think, is a valuable part of that that helps recognize people's autonomy. But I don't think that autonomy is sort of the end all and be all, that there are other public goods here that for data sharing, for quality improvement, for research and so on that have to be balanced, and that ultimately, we as patients, we the public benefit from quality improvement and research that benefits us personally down the road, and we, as the public, in many ways. And so I think we cannot, while autonomy is important, we have to balance that against other societal goods.

Kathleen Connor – Microsoft Health Solutions – Principal Program Manager
This is Kathleen. That's why I said outside of the bounds of what's allowed under HIPAA. I think I'm agreeing with you. I would agree with you.

Deven McGraw - Center for Democracy & Technology – Director
Yes. And I think that's the reason, so one of the reasons why I'm considering whether an additional layer of consent ought to be applied to these sort of intermediaries where we've started to scope out some of the – that are queriable or that are repository based and sort of a few other things that have come up is

because the primary data source still has data that is subject to access, use, and disclosure under existing federal and state law, so if there was, for example, and I'm testing this out with you all, and so I'm fully expecting you to push back.

I mean, we're having a really robust discussion here about what a recommendation from us might look like. You know, you can still get research data from an individual provider, even if I have opted not to have my data accessible in my state's RHIO, for example. It's still in my doctor's files, and it's still subject to HIPAA and whatever is my applicable state law about who can access it and for what purposes, which includes public health, research, etc. And so that, you know, we're not, at least at this point, what's not on the table in my view is changing that for covered entity records.

Marianna Bledsoe – NIH – Deputy Associate Director
Then I would say, in terms of, if you're talking about using RHIOs for research purposes, and I think they would provide an extraordinarily valuable research tool, whether we're calling it, I don't know if we want to use the term RHIO or some other sort of repository. There are other … there may be other protections in place. While it may not be covered under HIPAA, and particularly is used for research such as the common rule, that would protect that data. I think what we're probably dealing with here is the fact that HIPAA doesn't cover everything that we would like it to cover.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
Yes. This is Dixie. Do I need to get into the queue?

Deven McGraw - Center for Democracy & Technology – Director
Yes. We'll make sure that Marianna is finished with her comment, and then you're next.

Marianna Bledsoe – NIH – Deputy Associate Director
No, I think I'm finished.

Deven McGraw - Center for Democracy & Technology – Director
Okay.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
I thought I heard a breath there, Marianna.

Deven McGraw - Center for Democracy & Technology – Director
Be careful about breathing on these calls.

Marianna Bledsoe – NIH – Deputy Associate Director
It's been tough, I'll tell you.

Deven McGraw - Center for Democracy & Technology – Director
Go ahead, Dixie.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
Yes, and actually I was thinking along the same lines as Marianna, before she said it. But I was thinking, combined with your point earlier, Deven, that we're not redoing HIPAA. I was thinking through, you know, what kinds of things are concerns to consumers that are not already covered in HIPAA because a lot of this is covered in HIPAA. And I think that there are four things.

One is one that we've spoken about before is opt in, opt out of an HIE. That's not covered in HIPAA yet. But the HIE itself is a business associate thanks to ARRA, so what it does with information is covered under HIPAA.

The second thing is the granularity of control is not really specified in HIPAA. The third is one of Deborah Peel's favorite attributes or whatever, you know, is de-identification. If you've heard her talk, you know that she kind of dismisses the idea that your de-identified data could be used for pharmaceutical research, etc. So the question arises is, should a patient – you know, from her arguments, a natural question is, should a patient have to give consent for their data to be de-identified and used for research or whatever.

Then the fourth thing is aggregation and data mining. And I think those, in my mind, are the four areas that cause people some concern and are beyond what HIPAA currently addresses, HIPAA and ARRA.

M
What did you mean by granularity, Dixie?

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
The granularity of control, you kind of hear people sometimes talk about, well, should the control be at the level of a data element or a segment of a CDA, or should it apply to the entire patient record, and that's really not addressed.

Deven McGraw - Center for Democracy & Technology – Director
Well, it is.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
Okay.

Deven McGraw - Center for Democracy & Technology – Director
It's arguably addressed. It is, you do not need consent for treatment, payment, and operations.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
No, but I mean, if I take – sometimes you go, okay, my segmentation. That's what I mean by that. What this group calls segmentation, I call granularity.

Kathleen Connor – Microsoft Health Solutions – Principal Program Manager
This is Kathleen. I wanted to ask Dixie a question about, if that's okay.

Deven McGraw - Center for Democracy & Technology – Director
Yes. No, go ahead. Although I have to say, you know, Dixie sort of laid on the table four areas that she thinks are not addressed by HIPAA. I want to be very careful that this is not straying into a discussion about fixing HIPAA or other issues that are later in our work plan to be resolved.

Kathleen Connor – Microsoft Health Solutions – Principal Program Manager
No….

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
Yes. Yes, I meant to really kind of piggyback on your comment, Deven, that I totally agree. We aren't here to reinvent HIPAA, so we shouldn't be arguing about things that are already covered under HIPAA.

Kathleen Connor – Microsoft Health Solutions – Principal Program Manager
I was just going to ask a clarification.

Deven McGraw - Center for Democracy & Technology – Director
Go ahead, Kathleen.

Kathleen Connor – Microsoft Health Solutions – Principal Program Manager
When you said that HIEs are now covered as business associates from HITECH, so they're covered by HIPAA, I wanted to make sure that you meant they're covered by HIPAA as a business associate with respect to what they're doing for a covered entity and not just anything they're doing.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
Yes, that's true.

Kathleen Connor – Microsoft Health Solutions – Principal Program Manager
Thank you.

Marianna Bledsoe – NIH – Deputy Associate Director
This is Marianna. I would just like to add to, I think, what Dixie was saying in that I think we should look at what isn't covered by – what are we worried about that isn't covered by existing regulation, and is there – and there are different ways of looking at that. They're saying, you know, we could say what additional protections need to be built in and under what conditions do we need to consent or otherwise educate the patient about what's happening.

Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO
Yes. This is Paul. Can I get in the queue?

Deven McGraw - Center for Democracy & Technology – Director
Yes. Go right ahead, Paul.

Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO
So I'd like to try to answer that question using the expectation test. I expect my information to go to my provider, and to go to payers, and to go to specialists. Now if it goes to the intermediary, and let's say somebody is doing something on behalf of the covered entity as a business associate, that's transparent to me, but I assume my covered entity, my provider is taking care of that. I would be extremely surprised, shocked, and insulted if the business associate, whatever they are, whether it's a commercial PHR or an HIE, intermediary.

Did the business associate … had some business model on the side to reuse the data that they happen to now have whether it's to market to me, to sell to pharmaceutical or insurance, whatever? So that's what I'm afraid of, and I think that's what Deven was saying she's afraid of. And yet, there's nothing specific. I mean, there's some gray interpretation. There's nothing specific to prevent non-HIPAA covered entities from doing other things. I'm not trying to fix HIPAA. I'm just saying, that's what I'm afraid of.

Kathleen Connor – Microsoft Health Solutions – Principal Program Manager
This is Kathleen.

Mike DeCarlo – BlueCross BlueShield
Can I get in the queue?

Deven McGraw - Center for Democracy & Technology – Director
Is that Mike DeCarlo?

Mike DeCarlo – BlueCross BlueShield
Go ahead, Kathleen. You're right. It is Mike.

Deven McGraw - Center for Democracy & Technology – Director
Okay. Let me have Mike first and then Kathleen.

Kathleen Connor – Microsoft Health Solutions – Principal Program Manager
That's fine.

Mike DeCarlo – BlueCross BlueShield
Thank you. All I want to do is endorse Paul's test, and I think we need a test in this process. Otherwise we're randomly picking our pet peeves or our anecdotal evidence or ideas that we're coming up with and trying to figure out whether or not it's something that needs to be addressed. If we have the test, as Paul has laid it out, I think we can be more definitive about the kinds of areas that need more control. And it's also a good test because it rests on the individual expectation, which, over time, we can adjust and raise. That's all I want to say.

Deven McGraw - Center for Democracy & Technology – Director
Very interesting point. Go ahead, Kathleen.

Kathleen Connor – Microsoft Health Solutions – Principal Program Manager
And I also like Paul's test. I think that Dixie pointed out a couple of places where Paul's test would risk falling down, and I think that there are several areas where ambiguity in what HIPAA allows under operations, etc. are areas that would also cross that test or fail that test. So I think we need to look at those scenarios and carve out which ones are outside of the bounds of HIPAA at this point. For example, using, if the business associate uses this information in a quasi treatment way, you know, where is the boundary?

Deven McGraw - Center for Democracy & Technology – Director
What do you mean by quasi treatment?

Kathleen Connor – Microsoft Health Solutions – Principal Program Manager
Well, an example would be the intermediary compiles this information and makes it available for, maybe even sells it to an HIE who can make it available to providers who may or may not have a treatment relationship with the subjects of those records.

Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO
And I'll add another one if I can.

Deven McGraw - Center for Democracy & Technology – Director
Yes, go ahead.

Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO
So using the expectation test, I also, as a patient, do not expect my data to go and be a part of an aggregate database because I didn't expect that to happen without my say. And I'll further characterize it, that's not the aggregate database for research. It's not for public health. And so somebody can make

money off of my data despite the fact that it may be not traceable back to me. Why does that violate expectation, and how could that turn around and cause me harm? It's because they can amass the data, a database where they can, one, let me just give one example.

They can figure out how to, without using the lawful, the things that are prohibited by law to discriminate against, to come up with other, and that's the traditional way they do this is to come up with other characteristics of features of individuals that are not unlawful to discriminate to use to discriminate against me. And they use those features to, let's say, provide insurance or provide a whole bunch of things. An individual could be very upset with that happening.

Deven McGraw - Center for Democracy & Technology – Director
I want to suggest some modification to the expectations test, which is it's becoming clear to me that we could use that test for every issue we're taking on as a workgroup as a litmus test for whether there are sufficient rules in place, whether it's consent or whether data is permitted to be used for certain purposes to meet patient's expectations. Of course, with the recognition, I think Mike is right, that those fluctuate over time and, as always, that for any individual patient that's somewhat hard to predict. But what I'm trying to do is to keep this conversation focused a bit on where we started because what we're aiming for is a set of recommendations on exchange models that might be beyond expectations and, therefore, require some additional rules, which might include additional consent, for example. But not, I mean, to me, Paul, quite frankly, it's a good point that you raise, but I think it's more appropriate to have that discussion when we talk about de-identified data than in this context.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
This is Dixie. I don't agree because I think that when people – people don't think about that until they – just if they're, you know, if I'm visiting. If a person is visiting their physician, they don't think about it. They only think about it in the context of the opportunity to aggregate data.

Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO
Yes, and let me add. So I think it was Kathleen that was asking the question: what are people afraid of? People are afraid of something happening they didn't expect. And I like Mike's addition, which says, and that may change over time, and that's what society is all about. All of a sudden, TSA could say they want this, that, and the other. And because of a bunch of terrorist attacks, we agree. You know, things can change over time, and that's built into this whole social process. But I think it is important to talk about at this point in terms of creating the rules for HIE is to understand who do we figure out what tests do we use and what policies would have to insure that people think that we're following their expectations.

Marianna Bledsoe – NIH – Deputy Associate Director
This is Marianna again. I'd like to add two additional modifications to the expectation test. One is the consideration of protection under existing law and also public good, public health benefits.

Deven McGraw - Center for Democracy & Technology – Director
Okay.

Paul Egerman – eScription – CEO
What does that mean, public good?

Kathleen Connor – Microsoft Health Solutions – Principal Program Manager
Well, for example, public health reporting and research. There are societal benefits that we accrue from exchange of data.

Deven McGraw - Center for Democracy & Technology – Director
Let Paul respond to that.

Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO
So applying the … test.

Deven McGraw - Center for Democracy & Technology – Director
Wait. I think that was Paul Egerman, right?

Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO
Sorry.

Paul Egerman – eScription – CEO
Yes. This is the other Paul.

Deven McGraw - Center for Democracy & Technology – Director
Yes, the other Paul.

Paul Egerman – eScription – CEO
I was looking at, if you look at public health, I mean, public health, if what you're talking about is reporting to some state public health agency, which is mandated by law, well then there's no issue about consent because there's state law. There's been a public debate, and that's how you define the public good. However, you can't define the public good based on a broad statement of saying research because that's how you get into the challenges that I think Paul Tang was referring to. In my research, I'm trying to find the people that'll cost me the least amount of money to insure. And I might have some arguments that I think that's the public good. So research is not necessarily the public good … it's not inherently good.

Kathleen Connor – Microsoft Health Solutions – Principal Program Manager
Right. That's certainly not what I meant, and certainly I was speaking more in the research realm, which is protected, like public health reporting is covered under existing law.

Deven McGraw - Center for Democracy & Technology – Director
Right. You know, I want to – I'm going to interrupt again only because where we started in this conversation was some level of comfort based on our patient expectations test with one-to-one exchange for stage one of meaningful use, which assumes there's nobody in the middle, and if there is a middle person, an intermediary, a facilitator, they're just doing the transport, and they're not accessing the data, and there's control of the data by the traditional data holder, and all of the rules that apply about what you can or can't do with de-identified data, when consent is needed for research, public health uses. We haven't changed them.

We're moving to a discussion about different types of exchange, which is quite relevant and on the table today because ONC just put out billions of dollars to states to create HIE. We'll call them HIEs, for lack of a better term. We've got discussions about NHIN Direct, which may be point-to-point. But, in some cases, intermediated, and it's unclear what at this point those intermediaries might have access to data about. And so I'm trying to get us focused on what is different from a meeting expectations standpoint about moving from one form to another versus so much of what the discussion that we've had about expectations, I might argue, absolutely no difference between one-to-one exchange and exchange through new vehicles that didn't exist until quite recently.

And it's not as though those aren't absolutely worthwhile issues. But if we continue to go down this path, we will not be able to resolve this issue of networks and transports and what additional requirements we'll make. Where there's some … identifying the areas of discomfort between one and the other form of exchange that might necessitate something more. And whether there's additional consent, additional rules, this is what I'm struggling with, folks, because otherwise we'll have a very – I'm not suggesting that those things that have been raised are at all off the table. I think we've identified a number of them in future work. But we have to bite this off in manageable pieces.

John Blair – Tacanic IPA – President & CEO
Deven, this is John Blair. When the health information exchange holds, which is not a covered entity, so outside of the covered entity, when the data is kept or held or maintained or is viewed.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
But if they're a business associate, that's done all the time.

John Blair – Tacanic IPA – President & CEO
No, but it's not held.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
Yes, it is. Yes, it is.

W
They have to do it for purposes that the covered entity has contracted with them for.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
Yes.

John Blair – Tacanic IPA – President & CEO
Yes, and I'm saying that that's when you move to another level.

W
I agree with you.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
Yes, and this is Dixie. I don't see any difference between point-to-point and HIE. I think the critical point is what we just now said. If they're aggregating the data for some non-explicit purpose, you know, if they're creating this repository that they could use for multiple things, and it's not being created to provide my care, then I think that that's the difference. It's not the point-to-point versus HIE model. It's why they're aggregating the data.

John Blair – Tacanic IPA – President & CEO
I think it's because they're not a covered entity, and they're let, and then other covered entity or other providers can then access that.

Joy Pritts – ONC – Chief Privacy Officer
This is Joy. There are provisions in the HITECH Act that say that health information organizations may not be covered entities, but they are to be considered business associates going forward.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
Right.

W
But isn't that with respect to a particular covered entity, not just – I mean … purpose specified by a particular covered entity.

Joy Pritts – ONC – Chief Privacy Officer
That's how the business associate agreements work, and that the intent, I believe, is to insure that the health information organization would be only conducting the functions that they are allowed to do under their business associate agreement.

W
That's for anything they would do outside of that is….

Joy Pritts – ONC – Chief Privacy Officer
That would be in violation of their business associate agreement, and the Act says that if they act beyond the business associate agreement, that's enforceable by OCR, not just under the contract.

W
They can do nothing outside of the business associate agreement contract, even if there's consent?

Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO
Let me ask a different question. Let's say the business associate wants them to prepare some reports, which is aggregate data. Now all of a sudden the business associate owns aggregate data. Are you saying that they cannot, in this, what they consider to be de-identified state, reuse and resell that aggregate data and be in compliance?

Adam Green – OCR
Deven, this is Adam. Can I jump in at some point?

Deven McGraw - Center for Democracy & Technology – Director
Of course you can, Adam.

Rachel Block – New York eHealth Collaborative – Executive Director
Yes. And, Deven, I'd like to respond to that as well.

Deven McGraw - Center for Democracy & Technology – Director
Okay. Go ahead, Adam.

Adam Green – OCR
The business associate has kind of an upper limit and a lower limit on what it can do. The upper limit is it cannot do anything that the covered entity itself would not be able to do. So that's the extent of what they can do with the PHI. But that's further limited by they may not use or disclose information contrary to their business associate agreement. I think the universe of everything a covered entity can do is shrunken down to what has been contracted for.

And the process of de-identification, you can't de-identify information without using the information to de-identify it, so your business associate agreement would have to specify that permissible use is de-identifying the information. If the business associate agreement does permit de-identification of the information, then it's no longer going to be covered by HIPAA, and a business associate can do anything they want with it.

Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO
That's the loophole, and that's where the money is being made.

Deven McGraw - Center for Democracy & Technology – Director
Okay. Rachel, was that you earlier?

Rachel Block – New York eHealth Collaborative – Executive Director
Yes, it was. Thanks. I just want to say that in addition to the correct legal answer that Adam just gave, there's also another level here, which is that these entities exist and provide these services based on participation agreements with the providers who we're talking about, relying on them to provide certain services for them. So I'm not going to speak to whether it is a loophole or isn't a loophole or what have you in terms of HIPAA because there are people much more qualified on the phone here to do that. But I just want to point out that the entity isn't doing things that those participation agreements don't in some way or another specifically address, so I think that one of the things that we might want to focus on at some point is addressing what we would like to see in those participation agreements that would make us feel more assured that the entity was operating in the way that I think Adam, from the legal point of view was describing we would consider to be appropriate.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
I would also say, you know, most of these HIEs look to their DURSA as their kind of, this is the agreement that governs how I operate, and the DURSA is more deals, I believe, with more aggregated data than a business associate agreement, which is just a contract for services.

Deven McGraw - Center for Democracy & Technology – Director
I just want to level set the discussion here. My understanding is that the DURSA, which is the Data Use and Reciprocal Services….

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
The torte agreement.

Deven McGraw - Center for Democracy & Technology – Director
Torte agreement was a vehicle created for the original NHIN to use, right?

M
Yes.

Deven McGraw - Center for Democracy & Technology – Director
So the original grantees for the NHIN as the concept of a network of networks, and maybe the federal agencies that were also involved, but I'm not aware. And while others may have used it as a model, I'm not aware that it's been blessed or endorsed as the model participation agreement. Whenever I hear DURSA, I don't think of it generically. I think of it as that agreement that was established for the original NHIN.

Rachel Block – New York eHealth Collaborative – Executive Director
Yes, Deven. This is Rachel. I would agree with that. The kind of participation agreement I'm talking about is something, which our RHIOs have entered into with their participant. We have general oversight into the contents of those agreements from the perspective that, in our rubric, those agreements have to bind the parties to follow the statewide policy guidance, which includes all of our consent policies, as well

as the uses of data policies that we have. So it is similar to a DURSA, but we certainly don't call it that. For better or worse, I do think that people view the term DURSA specifically in the context of NHIN.

Adam Green – OCR
This is Adam. The DURSA was explicitly crafted not to be a business associate agreement. There was significant discussion of that, and it was felt that the relationship between a provider and that provider's health information exchange, that is a business associate relationship. But then the DURSA was meant to be the relationship between a particular health information exchange and another health information exchange who are not acting on each other's behalves, so it does not have business associate provisions and does not address some of the limitations that we'd be talking about here.

Kathleen Connor – Microsoft Health Solutions – Principal Program Manager
This is Kathleen. That raises another topic about the exchange pattern, which is the HIE-to-HIE relationships and exchanges and how to address that is a loophole.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
Yes.

M
Yes.

Gayle Harrell – Florida – Former State Legislator
Big loophole.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
Yes. I also – this is Dixie again. The whole idea of de-identification because I do hear this brought up by Deborah all the time.

Deven McGraw - Center for Democracy & Technology – Director
I'm going to stop you only because I've heard from folks on the phone, and I'm going to try to synthesize some material that's related to these different forms of sort of data access, use, and disclosure. But I don't want to dive too deep down this de-identification hole. We could be here. We just have a few minutes left in this call before opening it up to public comment, and it's just an issue with a lot of tentacles, so I'm going to ask if you can hold off on it.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
Yes. That's fine. I agree.

Deven McGraw - Center for Democracy & Technology – Director
Much appreciated. Thank you. I know it's a tough one. Inevitably, trying to bite this stuff off in small chunks, it's very hard to do because everything is obviously interrelated.

W
I think, Deven, if I could just summarize the thought I was trying to express earlier that I think there is a big difference between viewing these HIE entities as somehow sort of commercial entities who are sort of free willing, out in the marketplace, you know, selling this and collecting that, versus entities, which exist specifically by virtue of the agreements that they have with the participants, and that those agreements specify the role of the entity and the protections, which are expected to be applied to data used in conjunction with those services. I think, at some point, we should just explore a little bit of where does that, which is separate from the consent policy, right? So where does the concept of the response, the

roles and responsibilities of that entity as defined in those agreements take us, and what kind of overarching policy or governance structure is necessary to get there.

Deven McGraw - Center for Democracy & Technology – Director
I think that's a great comment, Rachel, in part because it gets us back to, you know, the frame that we've always started with, which is that the consent piece. We understand how important the consent piece is, but it's nested within a lot of very important decisions about who can access data and for what purposes that are equally as important and, I think, some people would argue more so, but others would not. But nevertheless, it's all part of a framework, and perhaps what makes this issue so difficult is that we haven't really sort of pinned down, at least at some level beyond near principle, what our expectations are for what the sort of rules of the road that these exchanges, networks, intermediaries, whatever we want to call them have to operate under. And maybe we need to tackle it at that level at least initially, either as or before we can really have a serious consent discussion. I think my preference would be to try to move forward on multiple different fronts if we can handle it. But I do, you know, the interrelatedness of all of this just keeps coming back.

Marianna Bledsoe – NIH – Deputy Associate Director
Deven, this is Marianna. I think you raise an excellent point, but that at least those two discussions have to go hand-in-hand.

Deven McGraw - Center for Democracy & Technology – Director
Right. Yes, I actually started with a document that was much longer that tried to outline some of that stuff, and then since I didn't get it down until last night, I didn't want to overwhelm people with the paperwork. Be prepared to have a little bit more to chew on and more time before our next call. Would it also be helpful for folks to be able to read, for example, just what the rules are on business associates?

Gayle Harrell – Florida – Former State Legislator
Yes, that would be very helpful.

W
As well as data aggregation when a single business associate operates on behalf of multiple covered entities, for example.

Deven McGraw - Center for Democracy & Technology – Director
Okay.

Adam Green – OCR
Deven, do you want me to work with you on that?

Deven McGraw - Center for Democracy & Technology – Director
I would love that, Adam.

Adam Green – Progressive Chain Campaign Committee – Cofounder
I'd be happy to.

Deven McGraw - Center for Democracy & Technology – Director
Thank you. Yes. I think having, at least based on the current business associate regulations, a sense of what the rules are, you know, that are already in place, I think, is going to be very helpful for us. All right. Well, I'm going to open up the phone lines in a minute, but I also want to ask folks to, I mean, I think we've had – we've delved into a lot of really interesting areas. I've been somewhat tough with you guys

trying to keep this focused, but I have staff who take copious notes on these calls so that when Rachel and I sit down with staff to pull together materials to guide our discussion in the next call, we try to make sure we haven't missed any of the points that people brought up. But obviously we try to organize it so we can continue to make progress on this.

And so I invite you to, as always, just send me e-mails, and just send e-mails to the workgroup as a whole, if you'd like, but just being mindful that we want to try to avoid having robust e-mail debates because not everybody is able to be present, so we won't ever resolve anything by e-mail, but I certainly would never cut folks off from sharing things with their workgroup colleagues. And I certainly, you know, as you continue to think about this, if you haven't read the ONC white paper on consent, it is long, but I think it's thoughtful, and it could be helpful. Similarly, the NCVHS set of recommendations for which the link was circulated, folks probably didn't have time to delve into that in detail. I think those pieces are helpful as well to have for this discussion. Any other thoughts before we open it up to the public?

Kathleen Connor – Microsoft Health Solutions – Principal Program Manager
This is Kathleen. If Rachel could give us some examples of these agreements, I think that would be helpful as well.

Rachel Block – New York eHealth Collaborative – Executive Director
Yes. I'll give Deven two things. One is a couple of samples of participation agreements, which our different groups have used. Again, we didn't prescribe a single form. We just said that there needs to be some standardized content, as it relates to compliance with state policy. And then the rest of it was really constructed by the lawyers, so you can just imagine. But anyway, and we also have some vendor contract language, which also talks about how we – which I the means that we use to make sure that every vendor providing services in New York State using state dollars will comply with the state policies as well.

Deven McGraw - Center for Democracy & Technology – Director
Anything else? Okay. Let's, Judy—

Judy Sparrow – Office of the National Coordinator – Executive Director
Yes. Operator, let's see if anybody wants to make a comment in the public. Just a reminder, Deven, our next workgroup call is April 26th.

Operator
We have a question from Dr. Peel.

Deborah Peel – Patient Privacy Rights – Founder & Chair
Hello, everybody. I couldn't help hearing my name taken in vain, but what I would really like to start with because I am absolutely thrilled about the tremendous emphasis on what patients expect. Maybe Paul introduced it, that concept, but it's tremendous. It's tremendous, and in a nutshell, we believe that what patients expect are that HIEs and NHINs are going to support what they know, which is one-to-one exchange of information.

In support of that, I hope that in addition to all the things you're reviewing, that you would look at a paper in *Health Affairs* by Don Berwick. As you know, he is the nominee for the head of CMS, and that paper is called *What Patient Centered Should Mean: Confessions of an Extremist*, a seasoned clinician an expert fears the loss of his humanity, he should become a patient. And, you know, he is characterizing himself as an extremist, which I think finally puts me in a really nice camp. I want to be in his camp.

Here's what he says in this paper. In a patient centered world, here's a direct quote. "Medical records would belong to patients. Clinicians, rather than patients, would need to have permission to gain access to them." That's his quote, and I think you'd be very, very interested in the other radical concepts that he thinks are going to be required for patient centered care. But I think that the point really is that patient control over personal health information is no longer the extremist position.

I would like to do another thing, which is correct the misconceptions about HIPAA and revisiting HIPAA. It's critical to remember that the original HIPAA privacy rule, which was in effect for about a year when first implemented by President Bush, actually had a right of consent in it. It was required for the exchange of PHI for TPO. That's how it was. The original debates came down strongly, totally in favor of informed consent. And it was only about a year later when the rule was amended, and this was not noticed particularly by anyone from the national media, to Congress, to the public.

It was never really reported on, but it was a rulemaking process, not the legislative process, you know, that eliminated consent. And so it's not accurate to say, well, it is accurate to talk about whether HIPAA needs to be revisited or not, but whatever you're going to do about that, you should recognize that the original legislative process was, and the rule for one year did vest patients with the right of consent, and it was essentially changed in secret because hardly anyone followed these kinds of processes.

The other thing that I want to talk to you about is that it hasn't been all that recent in history that we really got strong, ethical controls over experimentation and research. You know the Nuremberg Code, I think, is where a lot of that began, but we really only began to pay a lot of attention to research and consent in this country in the '50s and '60s with things like Tuskegee and also what happened with Henrietta Lacks and the helo cells. I mean, there were actually doctors injecting patients with her cancer cells to see what would happen without feeling like they had to tell patients anything.

We have only fairly recently in history really understood the autonomous rights of individuals has to be present before you can do research, and so is it clear what people expect? Yes. I mean, I think you all have had a very robust discussion about that, and you've also had discussions about whether those expectations should change. And they may change. It's possible. They may change, but their expectations today are at least for majorities of people really are control. Control over information in all of the ways that you've talked about, and so we think that the solution to what HIEs and NHINs should support is what people expect, and anything less than that is going to create havoc.

I mean, we see this with the kind of havoc that's been created with things like Google Buzz and what's the other one, and the Facebook changes and privacy policies. There isn't even really – people don't really even have the kind of rights they do over digital information about them in other sectors of their lives, but even there where they don't have the kind of strong privacy rights we have in health information, they get very, very angry when they believe that their information is being shared in ways that they had no idea about. And so we'd really like to recommend that you follow what you're saying, that one-to-one and direct relationships with people are what are trusted.

Third parties that no one has ever heard of, that they don't know their place in their healthcare system are not trusted, and it would take a lot to trust them. Furthermore, even if we have legal agreements that lock all of the various handlers, transfers of data, etc. into supposedly doing the right thing, we've got to remember, this information is unbelievably commercially valuable. It is a major, major commodity that's bought and sold. Just in the area of prescription records, the business is worth probably at least between $2 billion and $15 billion or more per year, and so even if we have contracts and rules in place, people are not going to necessarily follow them. And we have to have ways of having all of these people and

companies certified and audited to make sure that they're actually doing what the contracts say. I'm done.

Judy Sparrow – Office of the National Coordinator – Executive Director
Thank you, Dr. Peel. Anybody else on the line?

Operator
Yes, we have another comment from Lorraine Fernandes.

Lorraine Fernandes – IBM – VP & Healthcare Industry Ambassador
Thank you. This is Lorraine Fernandes from IBM. And I just offer a couple of comments and insight. Number one is commendations to Rachel and the others like John who are working with this today. I think their insight and viewpoints for those organizations that are really exchanging data today are very important, so I'd love to see that dialog continue.

And number two is just to alert everybody. I was at a Webinar earlier this week where some members of, let's see, they were on the NHIN workgroup, and I think one of the people was on HIT Standards Committee. And they were specifically talking about how the DURSA would be used on a go forward basis. And I heard the term DURSA light put out there that with NHIN Direct, a DURSA light might need to be considered, so you'll probably want to loop to others out there to make sure the conversations are synchronized. Thank you.

Judy Sparrow – Office of the National Coordinator – Executive Director
Thank you. Anybody else?

Operator
There are no more comments.

Judy Sparrow – Office of the National Coordinator – Executive Director
Thank you. Deven?

Deven McGraw - Center for Democracy & Technology – Director
Okay. We will get folks the John Berwick article. If you haven't read it, we'll at least find you a link to it. And again, Rachel, thank you for offering the participation agreements. We will endeavor to get you all materials more in advance so we can all be better prepared for the next call. Thank you for your time and your very good comments, as always.

Gayle Harrell – Florida – Former State Legislator
Yes. Thank you.

Public Comment Received During the Meeting

1. Rachel's comments are a good reminder that what "we" may see as safe and secure. It may meet all of "our" security and privacy requirements…But what information needs to be carried through the transaction for reporting to the patient…say about who the individual provider is… that may not be required just to have secure exchange.

4. Paul's expectation test is a great point. There is an expectation as a consumer that exchange is achieved securely and protected. Whatever the limits that the "system" has…I as a patient have an expectation that I can review and understand the data disclosure information that tells me what has happened within and to my records. I understand that I as a patient need more information than what may doctor or other provider needs to see. What has to be shown the consumer so that the consumer is comfortable? If we do not address now then the systems design and technical underpinning might not exist to address these consumer expectations.